



Food and Drug Administration  
555 Winderley Pl., Ste. 200  
Maitland, FL 32751

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

**WARNING LETTER**

**FLA-07-08**

January 8, 2007

Robert N. Haddad, President  
Caribbean Ventures Inc.  
7200 SW 8<sup>th</sup> Street  
Miami Florida 33144

Dear Mr. Haddad:

We inspected your seafood importer establishment, located at 7200 SW 8<sup>th</sup> Street, Miami Florida 33144 on December 4 and 5, 2006. We found that you have a serious violation of the seafood Hazard Analysis and Critical Control Point (HACCP) regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR Part 123). The specific requirements for imported fish and fishery products are set out in 21 CFR 123.12. As an importer of fish or fishery products, you must operate in accordance with the requirements of Part 123. In accordance with 21 CFR 123.12(d), there must be evidence that all fish and fishery products offered for entry into the United States have been processed under conditions that comply with 21 CFR Part 123. If assurances do not exist that the imported fish or fishery product has been processed under conditions that are equivalent to those required of domestic processors under 21 CFR Part 123, the fish or fishery products will appear to be adulterated under Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4) and will be denied entry. Because our inspection identified a serious violation for 21 CFR Part 123, your imported fishery products such as, king mackerel and pacific lobster tails are adulterated under Section 402(a)(4) of the Act (21 U.S.C. § 342(a)(4)), in that they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. You may find the Act, the seafood HACCP regulation and the Fish and Fisheries Products Hazards & Controls Guidance through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

Your significant violation is as follows:

You must implement an affirmative step which ensures that the fish and fishery product (s) you import are processed in accordance with the seafood HACCP regulation, to comply with 21 CFR 123.12 (a) (2) (ii). However, your firm did not perform an affirmative step for king mackerel manufactured by [REDACTED] and pacific lobster tails manufactured by [REDACTED]

We acknowledge receipt of your response letter dated December 21, 2006. This response letter fails to adequately address the aforementioned serious violation in that:

1. The HACCP plans from [REDACTED] are inadequate in that they are not in English. If your firm chooses to retain a foreign supplier's HACCP plan as part of an affirmative step, then your firm must maintain on file a copy, in English, of the foreign processor's HACCP plan, and a written guarantee from the foreign processor that the imported fish or fishery product is processed in accordance with the requirements of 21 CFR 123.12 (a) (2) (ii) (D).
2. You supplied an inadequate letter of guarantee from one of your foreign processors, [REDACTED]
  - The letter is undated.
  - The letter does not include or specify the regulations of 21 CFR 123.
3. The HACCP plans from [REDACTED] are inadequate in that:
  - The foreign processor does not identify the species of fish in the HACCP plans. Therefore, we are not able to determine the hazard to be controlled.
4. There is no letter of guarantee included with your submitted HACCP plans from [REDACTED]

You stated in your response that your firm is no longer importing king fish (king mackerel). However, you submitted inadequate HACCP plans for unidentified fish from your foreign supplier, [REDACTED]. We are unable to adequately determine if you have, in fact, ceased importing king fish as stated. Clarification of whether or not king fish is imported needs to be determined.

We may take further action if you do not promptly correct this violation. For instance, we may take further action to refuse admission of your imported fish or fishery products under Section 801(a) of the Act (21 U.S.C. § 381(a)), including placing them on "detention without physical examination," seize your product(s) and/or enjoin your firm from further violating the Act.

In addition our inspector found that you have failed to establish product specifications and failed to establish written verification procedures for any of your seafood products you import.

You should respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct this violation. You should include in your response documentation, such as HACCP and importer verification records and records that document the performance and results of your firm's affirmative steps, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, you should explain the reason for your delay and state when you will correct any remaining violations.

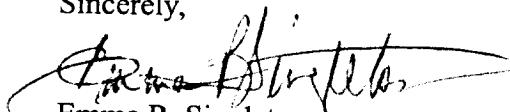
Caribbean Ventures, Inc.

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This letter may not list all the violations at your facility. You are responsible for ensuring that your seafood importer establishment operates in compliance with the Act and the seafood HACCP regulation (21 CFR Part 123). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations for the fish or fishery products that you import into the United States.

Please send your reply to the Food and Drug Administration, Attention: Kelly I. Anderson, 555 Winderley Place, Suite #200, Maitland, Florida 32751. If you have questions regarding any issues in this letter, please contact Kelly I. Anderson at (407)-475-4731.

Sincerely,

A handwritten signature in black ink, appearing to read "Emma R. Singleton", with a long horizontal flourish extending to the right.

Emma R. Singleton  
Director, Florida District